

# Nonbeverage Products Laboratory Overview

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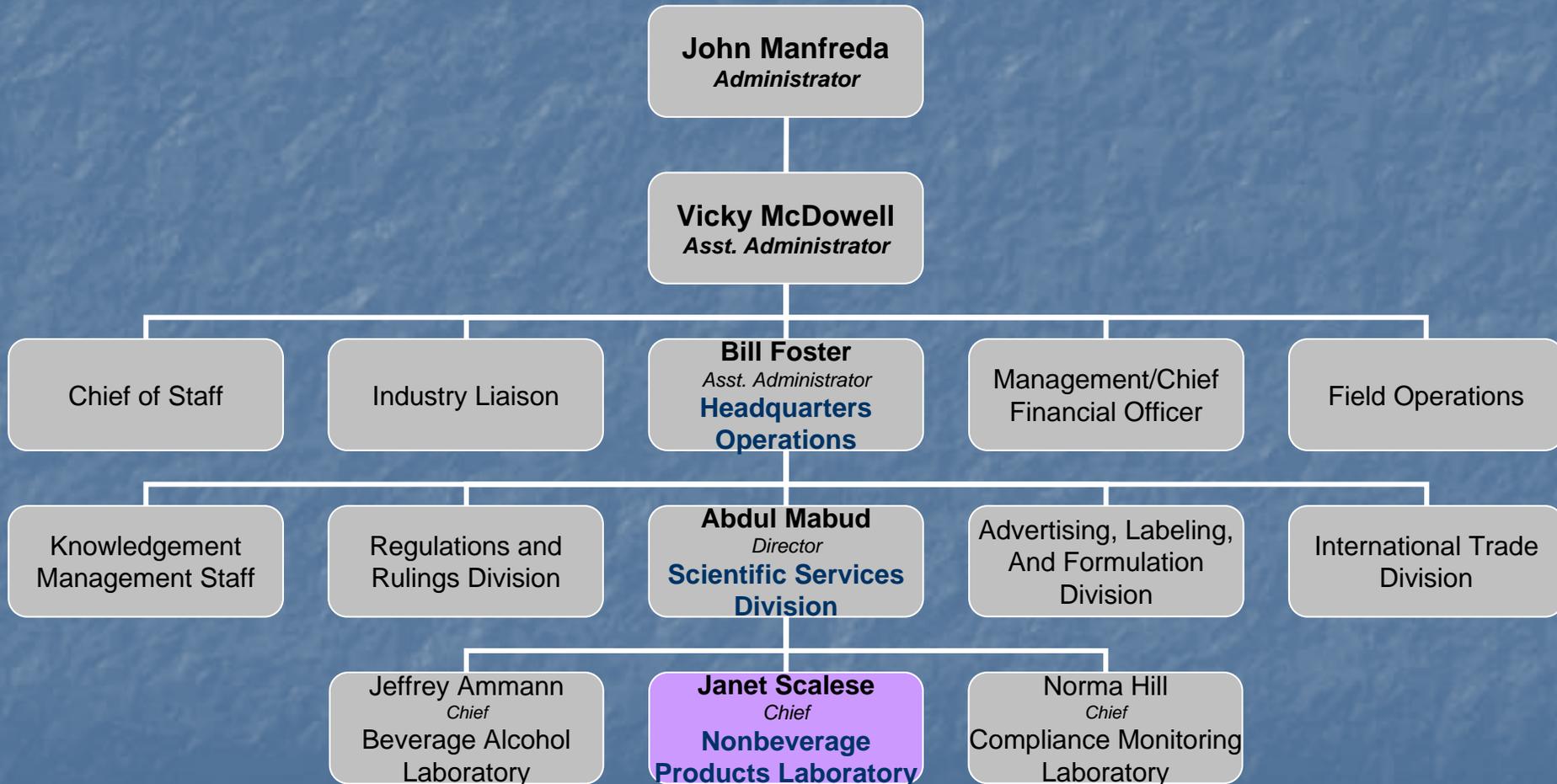
# Mission



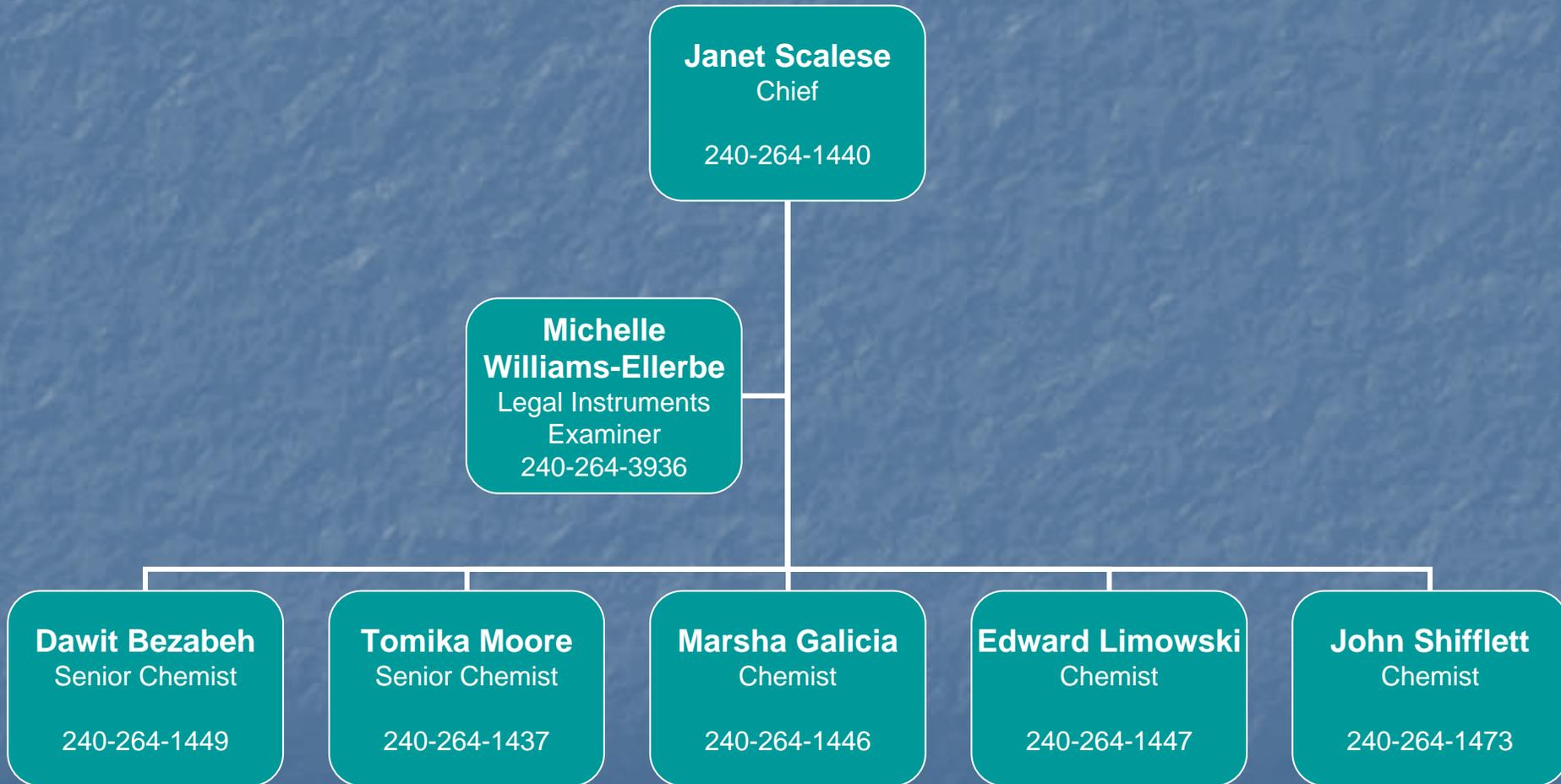
To provide the quality data and technical support required by TTB and industry members to **protect the public** and **collect the revenue** through processing formulas and analyzing samples for nonbeverage and tobacco products



# Organization



# NPL Organization





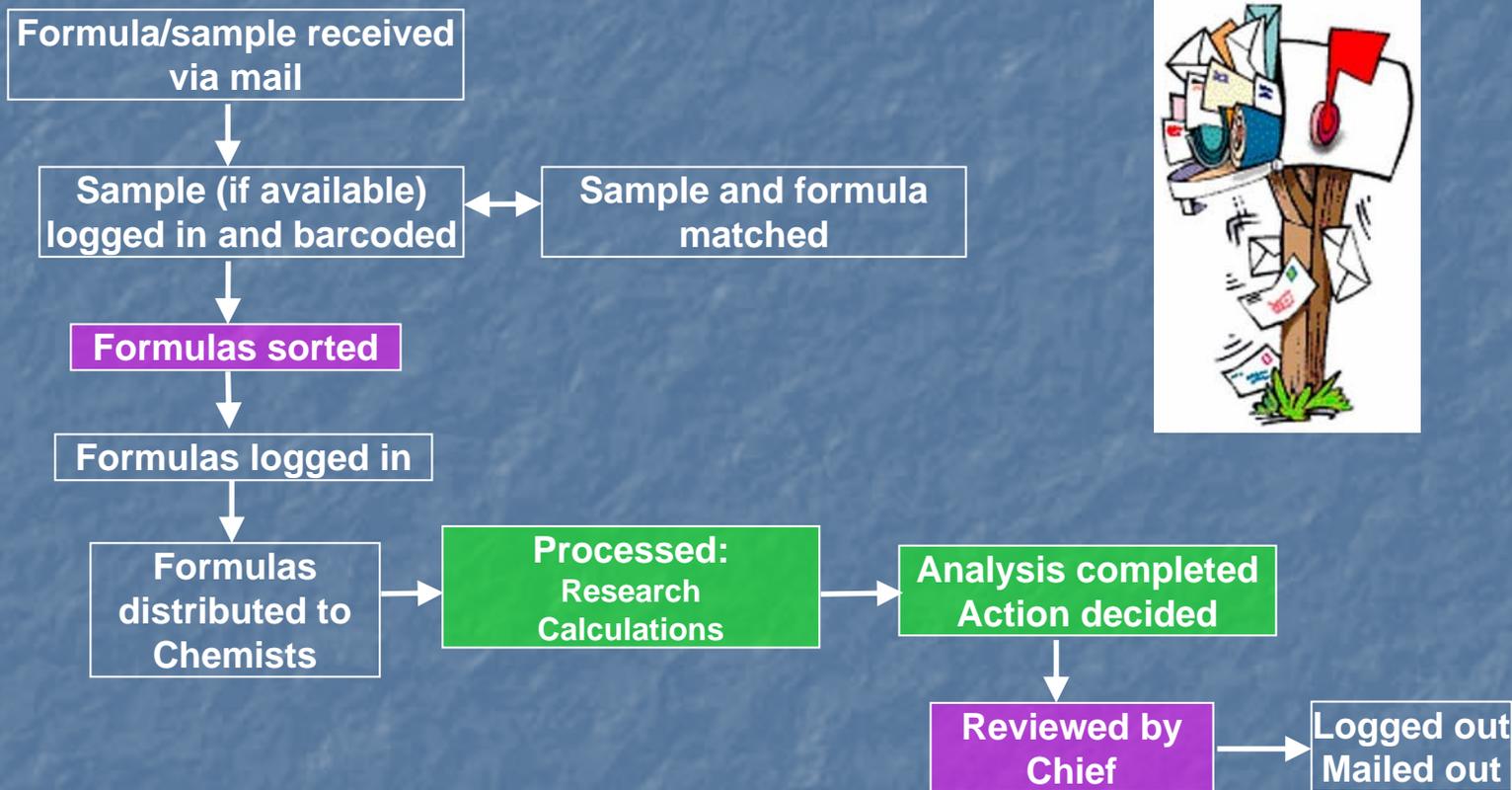
# Products



- Nonbeverage (Drawback) Alcohol
  - Food, flavor, medicine, medicinal preparations, perfumes
  - Manufacturer pays excise tax on purchase of ethanol
  - File formula and claims for return on some of the tax
- Specially Denatured Alcohol (SDA)
  - Alcohol containing other chemicals which denatures it to make it unfit (27 CFR Part 21)
  - Companies must have permit and approved formula
- Tobacco
  - Laboratory analysis to determine tax classification



# The Fate of a Formula





# Actions

- **APPROVED (Domestic)** – alcohol eligible for drawback, unfit for beverage purposes
- **NO ACTION (Domestic)** – no alcohol eligible for drawback, unfit for beverage purposes
- **APPROVED/NO ACTION (Foreign)** – alcohol eligible for 5010 tax credit, unfit for beverage purposes
- **DISAPPROVED (Domestic)** – alcohol is NOT ELIGIBLE for drawback, fit for beverage purposes, cannot be sold to another company
- **DISAPPROVED (Foreign)** – alcohol NOT ELIGIBLE for 5010 tax credit, fit for beverage purposes
- **RETURNED** – sample needed, information not complete, etc.





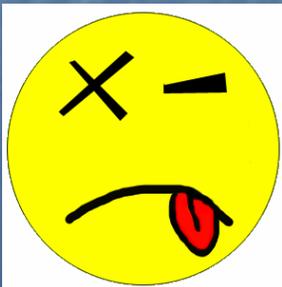
# “Fitness”

- Fit for beverage purposes = the average person might mistake the product for an alcoholic beverage
- Evaluation of fitness
  - Evaluate formula on paper using guidelines
  - Analyze ingredients
  - As a last resort, dilute to 15% EtOH and taste



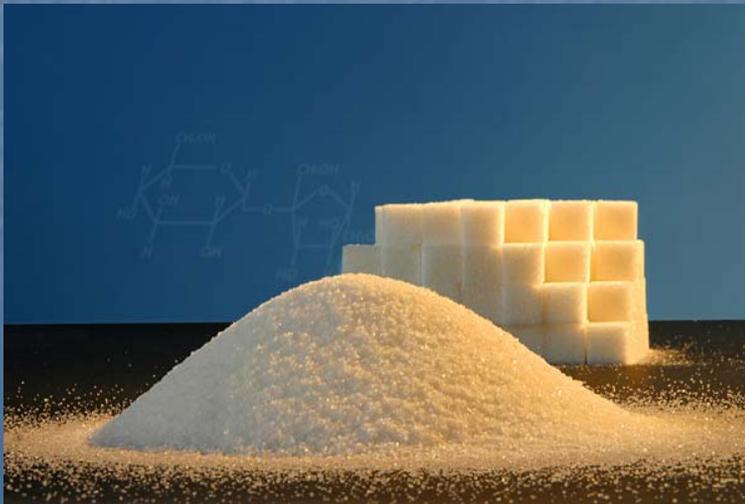
# Some Guidelines for “Unfitness”

Propylene Glycol	volume propylene glycol $\geq$ volume ethanol (based on upper limit in Item 10)
Salt	3.21 g salt/100 mL at 45% v/v ethanol
Vanillin	1 wt oz/gal at 30% v/v ethanol
Ethyl Vanillin	0.4 wt oz/gal at 30% v/v ethanol
Maltol	5% wt at 90% v/v ethanol



# Exception to the Guidelines

- The addition of sugar, glycerin, high fructose corn syrup, juices or other similar ingredient may mask the “unfitness”
- Samples must be tasted for evaluation



# Helpful Tips

- Statement of reason for unfitness on formula, e.g. "The formula is unfit because it contains 1% benzaldehyde"
- Disclosure of ingredients that may cause unfitness
- Internal taste panel



# ALL Limited Ingredients MUST BE DISCLOSED

- Ingredients directly added
- From other sources (e.g., solid extracts)
- Refer to 21 CFR Part 184  
Propylene Glycol, Acetic Acid, etc.
- TTB Limited Ingredients  
Synthetic Vanillin, Synthetic Maltol,  
Ethyl Maltol, Ethyl Vanillin





# Prohibited Ingredients

- Refer to 21 CFR Part 189
  - Calamus
  - Cinnamyl anthranilate
  - Coumarin
  - Cyclamate
  - Safrole
  - Thujone





# Allowed Colors

- Certified Colors – synthetic dyes
  - FD&C Blue #1
  - FD&C Green #3
  - FD&C Red #40
- Non-Certified Colors – natural coloring agents
  - Caramel
  - Beta Carotene
  - Titanium Dioxide





# Botanicals

- Botanical use in flavors must comply with food law and regulations
  - 21 CFR 172.510, 182.10, 182.20
  - GRAS Notices (e.g. Notice 18 – mesquite wood extract)
- If not listed in CFR or GRAS notice, need to go through GRAS Notification Program for GRAS determination
- Examples of problem botanicals:
  - Betel nut (*Areca catechu*)
  - *Lycium chinense*
  - *Polygonum multiflorum*
  - *Schisandra chinensis*
  - *Astragalus membranaceus*
  - *Sambucus latipinna*
  - *Stevia rebaudiana*





# Vanilla Extracts/Flavors



- Must meet standard of identity for approval (Refer to 21 CFR Part 169.175)
- 1 unit of vanilla beans = 13.35 oz at 25% moisture
- Info needed: bean moisture content, yield, fold, process, recovered ethanol, disposal of spent beans
  - Extracts
    - 1X = 1 unit/gallon, >35% v/v EtOH
    - Concentrated = 2+ units/gal, >35% v/v EtOH
    - May also contain glycerin, propylene glycol, sugar, dextrose, and/or corn syrup
    - >45% v/v ethanol subject to organoleptic evaluation
  - Flavors
    - 1X = 1 unit/gallon, <35% v/v EtOH
    - Concentrated = 2+ units/gal, <35% v/v EtOH

